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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**World Trade Center Health Program; Petition 007--Autoimmune Diseases; Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

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**SUMMARY:** On April 6, 2015, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 007) to add certain autoimmune diseases, including rheumatoid arthritis and connective tissues diseases, to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add certain autoimmune diseases to the List. The Administrator finds that insufficient evidence exists to request a recommendation of

the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-46, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the

Public Health Service Act (PHS Act) to add Title XXXIII<sup>1</sup> establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to § 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 60 calendar days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four

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<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

actions described in § 3312(a)(6)(B) and 42 CFR 88.17: (i) request a recommendation of the STAC; (ii) publish a proposed rule in the Federal Register to add such health condition; (iii) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the Federal Register a determination that insufficient evidence exists to take action under (i) through (iii) above.

#### B. Petition 007

On April 6, 2015, the Administrator received a petition to add "autoimmune diseases, such as Rheumatoid Arthritis" to the List (Petition 007).<sup>2</sup> The petition was submitted by a WTC Health Program member who responded to the September 11, 2001, terrorist attacks in New York City. The petitioner indicated that she has been diagnosed with rheumatoid arthritis, an autoimmune disorder, and is currently receiving treatment for a number of other WTC-related health conditions. The petitioner described an article published in the Journal of Arthritis and Rheumatology by Webber et al. [2015],<sup>3</sup> which was designed to

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<sup>2</sup> See Petition 007. WTC Health Program: Petitions Received.  
<http://www.cdc.gov/wtc/received.html>.

<sup>3</sup> Webber MP, Moir W, Zeig-Owens R, Glaser MS, Jaber N, Hall C, Berman J, Qayyum B, Loupasakis K, Kelly K, and Prezant DJ [2015]. Nested case-control study of selected

test the hypothesis that acute and chronic 9/11 work-related exposures were associated with the risk of certain new-onset systemic autoimmune diseases.

### C. Administrator's Determination on Petition 007

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions, published online in the Policies and Procedures section of the WTC Health Program website.<sup>4</sup> In accordance with the methodology, the Administrator directs the WTC Health Program Associate Director for Science (ADS) to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. The literature review includes published, peer-reviewed direct observational and/or epidemiological studies about the health condition among 9/11-exposed populations. The studies are reviewed for their relevance, quantity, and quality to provide a basis for deciding whether to propose adding the health condition to the List. Where the available evidence has the potential to provide a basis for

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systemic autoimmune diseases in World Trade Center rescue/recovery workers. *Journal of Arthritis & Rheumatology* 67(5):1369-1376.

<sup>4</sup> "Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions," John Howard MD, Administrator of the WTC Health Program, October 21, 2014. [http://www.cdc.gov/wtc/pdfs/WTCHP\\_PP\\_Adding\\_NonCancers\\_21\\_Oct\\_2014.pdf](http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf).

a decision, the ADS further assesses the scientific and medical evidence to determine whether a causal relationship between 9/11 exposures and the health condition is supported. A health condition may be added to the List if published, peer-reviewed direct observational or epidemiologic studies provide substantial support<sup>5</sup> for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If the evidence assessment provides only modest support<sup>6</sup> for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate additional published, peer-reviewed epidemiologic studies, conducted among non-9/11-exposed populations, evaluating associations between the health condition of interest and 9/11 agents.<sup>7</sup> If that additional assessment establishes substantial support for a causal relationship between a 9/11 agent or agents and the health condition, the health condition may be added to the List.

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<sup>5</sup> The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

<sup>6</sup> The modest evidence standard is met when the Program assesses all of the available, relevant information and determines with moderate confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

<sup>7</sup> 9/11 agents are chemical, physical, biological, or other agents or hazards reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area, or at the Pentagon site, or in Shanksville, Pennsylvania site as those locations are defined in 42 CFR 88.1.

In accordance with § 3312(a)(6)(B) of the PHS Act, 42 CFR 88.17, and the methodology for the addition of non-cancer health conditions to the List, the Administrator reviewed the evidence presented in Petition 007. Although the petitioner specifically requested the addition of certain autoimmune diseases such as rheumatoid arthritis and connective tissue diseases, the Administrator determined that the scope of the petition properly includes all of the autoimmune diseases identified in Webber et al. Accordingly, the ADS conducted a systematic literature search of the published scientific and medical literature for evidence of a causal relationship between 9/11 exposures and the autoimmune disorders described in Webber et al.<sup>8</sup> Those autoimmune disorders include: systemic lupus erythematosus, antiphospholipid syndrome, systemic sclerosis, inflammatory myositis, Sjögren's syndrome, rheumatoid arthritis, spondyloarthritis, granulomatosis with polyangiitis (Wegener's), and eosinophilic granulomatosis with polyangiitis (Churg-Strauss).

Other than the Webber study, the literature search yielded no relevant epidemiologic studies, and no direct observational studies.<sup>9</sup> In accordance with the methodology

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<sup>8</sup>Databases searched include: PubMed, Health & Safety Science Abstracts, Toxicology Abstracts, Toxline, Scopus, and Embase.

<sup>9</sup> Only epidemiologic studies of 9/11-exposed populations were considered to be relevant.

described above, the ADS assessed Webber et al. for quality and found significant limitations. Those limitations include low statistical power (due to the small number of cases); lack of information about other key confounders (e.g., family history of autoimmune diseases, history of viral infections or vaccination preceding diagnosis of the autoimmune disease, use of pharmaceutical agents and non-WTC-related exposures, both work-related and recreational); and potential for measurement error of chronic exposure (i.e., because a month of 9/11-related exposures was represented by at least 1 day spent at the WTC site, the duration variable did not differentiate between those with one day and those with many days of exposure in a given month; however, this measurement approach was non-differential between the cases and controls). Finally, participants were from the Fire Department of New York cohort only and predominantly a white male population which raises concern for generalizability to other 9/11-exposed groups, including female responders and survivors. Thus, the ADS concluded that the available information did not have the potential to form the basis for a decision on whether to propose adding the following conditions to the List of WTC-Related Health Conditions: systemic lupus

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erythematosus, antiphospholipid syndrome, systemic sclerosis, inflammatory myositis, Sjögren's syndrome, rheumatoid arthritis, spondyloarthritis, granulomatosis with polyangiitis (Wegener's), or eosinophilic granulomatosis with polyangiitis (Churg-Strauss).

The findings described above led the Administrator to determine that insufficient evidence exists to take further action, including either proposing the addition of the autoimmune diseases identified above to the List (pursuant to PHS Act, § 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, § 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, § 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 007 to add certain autoimmune diseases to the List of WTC-Related Health Conditions, including: systemic lupus erythematosus, antiphospholipid syndrome, systemic sclerosis, inflammatory myositis, Sjögren's syndrome, rheumatoid arthritis, spondyloarthritis, granulomatosis with polyangiitis (Wegener's), and eosinophilic

granulomatosis with polyangiitis (Churg-Strauss), is denied.

The Administrator is aware that another study of autoimmune diseases among World Trade Center enrollees is being conducted by the World Trade Center Health Registry; however, results from this study are not yet available in the scientific literature. The Administrator will monitor the scientific literature for publication of the results of this study and any other studies that address autoimmune diseases among World Trade Center exposed populations.

Dated: June 1, 2015

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John Howard, M.D.

Administrator, World Trade Center Health Program and  
Director, National Institute for Occupational Safety and  
Health, Centers for Disease Control and Prevention,  
Department of Health and Human Services

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